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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,606	05/23/2001	Julianna Lisziewicz	RGT 7028	2145

7590 09/10/2002

The Law Offices of Valerie E. Looper
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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	4

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/863,606	Applicant(s) LISZIEWICZ ET AL.	
	Examiner Michael Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Election/Restriction

Currently, claim 1 is generic to two patentably distinct inventions: 1) administering an antiretroviral drug therapy until viral replication is effectively suppressed and 2) administering gene delivery complex.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 15-21, drawn to administering an antiretroviral drug therapy until viral replication is effectively suppressed, classified in various classes and subclasses.

II. Claims 1 and 2, drawn to administering a gene delivery complex, wherein the genetic material is RNA, classified in class 514, subclass 44.

III. Claims 1 and 3-14, drawn to administering a gene delivery complex, wherein the genetic material is DNA, classified in class 514, subclass 44.

If applicants elect Group I, the phrase "of therapeutic genetic immunization" in the preamble and the phrase "and then administering a gene delivery complex... ...antigen presenting cell" will not be examined in claim 1.

If applicants elect Groups II or III, the phrase "administering an antiretroviral drug therapy until viral replication is effectively suppressed, and then" will not be examined in claim 1.

Upon electing a Group for examination, the claims must be amended to delete any non-elected subject matter from the pending claims.

Groups I and II or III are patentably distinct because administering a gene delivery complex is to induce a CTL response against a retrovirus while administering antiretroviral drug therapy is used to suppress viral replication. The burden required to search the two inventions together is undue as the structure of the genetic complex is materially separate than the antiretroviral drug therapy, the search for each is materially distinct and separate, and the breadth of each encompasses numerous divergent species (e.g. genetic material encompasses DNA or RNA, antiretroviral drug therapy encompasses protease inhibitors or reverse transcriptase inhibitors). Claim 1 requires administering antiretroviral drug therapy which implies administering the drug to a patient, while at the same time claim 1 merely requires "administering a gene delivery complex..." which is not limited to a patient. Therefore, the inventions are also distinct because "administering a gene delivery complex..." encompasses *in vitro* embodiments while "administering an antiretroviral drug therapy..." does not.

Groups II and III are patentably distinct because the purpose of administering RNA is to inhibit expression of a protein (antisense) while the purpose of administering DNA is to cause expression of protein encoded by the DNA. The structure of RNA and DNA is different and would require separate search. The burden required to search RNA and DNA together would be undue. The RNA does not require the DNA and the DNA does not require the RNA.

1. Claims 1 and 15-21 contain claims directed to the following patentably distinct species of

protease inhibitors: indinavir, saquinavir, ritonavir, nelfinavir, and GW141.

and

reverse transcriptase inhibitors: ddI, d4T, 3TC, AZT, delavirdine, abacavir, adefovir, nevirapine, efavirenz, lubocavir, PMPA, and PMEA.

If applicants elect Group I, applicant is required under 35 U.S.C. 121 to elect one protease inhibitor and one reverse transcriptase inhibitor for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 15-21 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL C. WILSON
PATENT EXAMINER